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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/785,532 01/17/97 GRAY

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EXAMINER

DAVIS, M

ART UNIT

PAPER NUMBER

1642

DATE MAILED:

10/19/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No.

08/785,532

Applicant(s)

Gray et al

Examiner

MINH TAM DAVIS

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on Aug 2, 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 26-63 is/are pending in the application.
- 4a) Of the above, claim(s) 29-36, 38-55, and 57-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-28, 37, 56, and 61-63 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other: \_\_\_\_\_

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Effective February 7, 1998, the Group Art Unit location has been changed, and the examiner of the application has been changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Minh-Tam Davis, Group Art Unit 1642.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Accordingly, claims 26-28, 37, 56, 61-63, SEQ ID NO:9 are being examined.

The following are the remaining rejections.

**REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, NEW MATTER**

Rejection under 35 USC 112, first paragraph of claims 26-28, 37, 56, 61-63 pertaining to new matter concerning a method for detecting the “absence” of neoplastic cells remains for reasons already of record in paper No.24.

Applicant argues that the Examiner has misread the preamble. The phrase “having an increased copy number” was intended to refer to the word “cells” rather than to the word “sample”. Applicant amends the claims so that it is clear that the phrase “having an increased copy number” refers to the word “cells” rather than to the word “sample”.

Applicant’s arguments set forth in paper No.27 have been considered but are not deemed to be persuasive for the following reasons:

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The specification does not disclose a method for the detection of the “absence” of neoplastic cells having an increased copy number of nucleic acid sequences at chromosome region 20q13.2.

**REJECTION UNDER 35 USC 112, SECOND PARAGRAPH, NEW REJECTION**

Claims 26-28, 37, 56, 61-63 are indefinite for the use of the language “relative” in claim 26. It is not clear the copy number is relative to what.

**REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, WRITTEN DESCRIPTION**

Rejection under 35 USC 112, first paragraph of claims 26, 37, pertaining to lack of a clear written description remains for reasons already of record in paper No.24.

Applicant recites the case law *Union Oil Co.v Atlantic Richfield et al*, arguing that the written description requirement does not require Applicant to describe exactly the subject matter claimed. Applicant asserts that the specification provides more than guidelines and functional description. Particular reference nucleic acid sequences are provided. Stringent hybridization conditions are defined and recited in the claims.

Applicant’s arguments set forth in paper No.27 have been considered but are not deemed to be persuasive for the following reasons:

The recitation of the case law *Union Oil Co.v Atlantic Richfield et al* is acknowledged.

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The claims still read on a method of detection of neoplastic cells having an increased copy number of nucleic acid sequences at chromosomal region 20q13.2, wherein numerous unrelated sequences that partially hybridize under the recited stringent conditions with the claimed nucleotide sequence would be detected. This rejection could be obviated by amending the claims, for example, to recite “fully hybridizes”.

**REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, ENABLEMENT**

1. Rejection under 35 USC 112, first paragraph of claims 26-28, 37, 56, 61-63 pertaining to lack of enablement for a method for detecting any neoplastic cells remains for reasons already of record in paper No.24.

It is noted that claim 27 was inadvertently not included in the rejection in previous Office action. It is clear from the rejection of the previous Office actions that claim 27 would be rejected as well.

Applicant argues that the Examiner improperly reads the claims. The claimed method is directed to detect the presence or absence of neoplastic cells having an increased copy number of nucleic acid sequences at chromosomal region 20q13.2. The specification teaches that cells comprising amplification at 20q13.2 are typically neoplastic. The Examiner has not offered evidence to indicate that cells comprising the recited amplification are not neoplastic. Moreover, Applicant recites criteria for undue experimentation as in *In re Wands*, and asserts that in the

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instant case, essentially no experimentation is necessary, since the breath of the claims are relatively narrow, being directed to a relatively simple hybridization assay.

Applicant's arguments set forth in paper No.27 have been considered but are not deemed to be persuasive for the following reasons:

The recitation of *In re Wands* is acknowledged.

The Examiner reads the claims broadly, but within reasonable interpretation. The breadth of the claims encompasses a method for detecting "any neoplastic cells", having an increased copy number of "any nucleic acid sequence" at chromosomal region 20q13.2, wherein said nucleic acid sequence at chromosomal region 20q13.2 could be totally unrelated to the claimed SEQ ID NO:9, comprising hybridizing with a probe that hybridizes under stringent conditions to the target sequence of SEQ ID NO:9, and wherein the presence of absence of any neoplastic cells having an increased copy number of "any nucleic acid sequence" at chromosomal region 20q13.2 could be determined by the relative copy number of "any nucleic acid" in chromosomal region 20q13.2. It is well known in the art, and as disclosed in the specification, the chromosomal region 20q13.2 encompass a large megabase region, and thus encompass numerous genes, which are completely unrelated to the claimed sequence of SEQ ID NO:9, which consists of only 2kb (specification, pages 2, 21). For example, a guanine nucleotide binding protein, G-s-alpha subunit gene, which has been mapped to the chromosomal region 20q13.2, and has an increased levels in peripheral leukocytes of manic patients, is totally unrelated to the claimed SEQ ID NO:9, a zinc finger gene (Le F et al, 1994, J Affective Disorders, 32(3): 187-195). Using a probe

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that selectively hybridizes to SEQ ID NO:9, one of skill in the art would not have expected that one could detect an increased copy number of a totally unrelated gene, at a distance from the claimed SEQ ID NO:9, although both genes are located in the chromosomal region 20q13.2, because a probe specific for SEQ ID NO:9 would not hybridize to any other unrelated gene.

Further, detection of overexpression of SEQ ID NO:9 in breast cancer cells could be not correlated with overexpression of SEQ ID NO:9 in any cancer having an increased copy number of any nucleic acid sequence located in the chromosomal region 20q13.2, but totally unrelated to SEQ ID NO:9, because different tumors have different etiology, and mechanisms of carcinogenesis, and because the role of SEQ ID NO:9 in any cancer, having an increased copy number of any nucleic acid sequence located in the chromosomal region 20q13.2, but totally unrelated to SEQ ID NO:9, is not known. Further, there is no indication that determining the relative copy number of any nucleic acid in chromosomal region 20q13.2, such as G-s-alpha subunit gene, which is correlated to manic conditions, would identify the presence of neoplastic cells.

#### **REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, SCOPE, NEW REJECTION**

Claims 26-28, 37, 56, 61-63 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for detecting in a breast cancer sample the presence of breast cancer comprising hybridizing under the recited stringent conditions a probe specific for SEQ ID NO:9 to a target polynucleotide in said breast cancer sample, does not

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reasonably provide enablement for a method for detecting in “any sample” the presence of neoplastic cells having an increased copy number of nucleic acid sequences at chromosome region 20q13.2, comprising hybridizing under the recited stringent conditions a probe specific for SEQ ID NO:9 to a target polynucleotide in said sample. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims.

Claims 26-28, 37, 56, 61-63 are drawn to a method for detecting in “a sample” the presence of neoplastic cells having an increased copy number of nucleic acid sequences at chromosome region 20q13.2, comprising hybridizing under the recited stringent conditions a probe specific for SEQ ID NO:9 to a target polynucleotide in said sample. The sample is from a patient with breast cancer.

Claims 26-28, 37, 56, 61-63 encompass a method for detecting in “any sample” the presence of neoplastic cells having an increased copy number of nucleic acid sequences at chromosome region 20q13.2, comprising hybridizing under the recited stringent conditions a probe specific for SEQ ID NO:9 to a target polynucleotide in said sample.

It is not clear how one could detect the presence of neoplastic cells having an increased copy number of nucleic acid sequences at chromosome region 20q13.2, using any sample, for example normal tissues, even from a patient with breast cancer.



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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Minh-Tam B. Davis whose telephone number is (703) 305-2008. The examiner can normally be reached on Monday-Friday from 9:30am to 3:30pm, except on Wednesday.

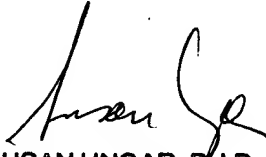
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tony Caputa, can be reached on (703) 308-3995. The fax phone number for this Group is (703) 308-4227.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0916.

Minh-Tam B. Davis

October 11, 2001



SUSAN UNGAR, PH.D  
PRIMARY EXAMINER